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10/784,401	02/23/2004	Peter M. Bonutti	780-A04-002-1	1827

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EXAMINER

TYSON, MELANIE RUANO

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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,401	Applicant(s) BONUTTI, PETER M.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-7, 17, 19, 24, 32-44, 46-50 and 54-73 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-7, 17, 19, 24, 32-44, 46-50 and 54-73 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This action is in response to the applicant's amendment received 24 November 2011. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 8-16, 18, 20-23, 25-31, 45, and 51-53 are cancelled. New claims 62-73 have been added.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the applicant's amendment received 24 November 2011.

The applicant will consider filing a terminal disclaimer if a conflict remains at the time all other issues regarding patentability are resolved.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose the magnetizable material creates a second magnetic

field. The specification simply describes one magnetic field generated at a time.

Therefore, this new limitation is considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 17, 19, 24, 32-39, 41-44, 46-49, 55-61, and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires the elongate body have a magnetically operable distal end, yet recites the engaging members being at or near the distal end. Since it is the engaging members that are disposed at or near the distal end that are magnetically operable, not the distal end of the elongate member itself, the claims are rendered indefinite. Claim 40 requires the elongate body having a non-mechanically actuated portion, yet also recites a magnetically operable distal end. Since it is the distal end itself that is non-mechanically actuated, and not a separate component of the elongate member itself, the claims are rendered indefinite. Appropriate corrections are required.

Furthermore, claims 55-57, 59, 61, and 73 recite the limitation "the implant".

There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 24, 32-34, 36-44, 46-50, 55-57, 59, 61-71, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. (U.S. Patent No. 5,925,064) and Hurst (U.S. Patent No. 4,437,362).

Meyers discloses a positioning apparatus (see entire document) comprising an elongate body (20) having a distal portion including magnetically operable first (40) and second (30) engaging members, the first engaging member configured to be movable relative to the second engaging member (via pivot pin 43), magnetizable material (magnets) disposed the engaging members, wherein the first engaging member is configured to be repelled relative to the second engaging member by a magnetic field alone (for example, see column 10, lines 9-11), and a holder connected to the first engaging member (portion between 46). Meyers fails to disclose whether the magnets may be specifically electromagnets.

Hurst also discloses a positioning apparatus (see entire document) comprising a first and second engaging members (for example, see Figure 1) movable relative to each other. Hurst teaches the engaging members may be biased apart by a spring or

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magnet, wherein the magnet may be a permanent type or an electromagnet (for example, see column 6, lines 10-15). The substitution of one known element (an electromagnet) for another (one or both of Meyers' permanent magnets) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the type of magnets utilized would have yielded predictable results, namely, a controllable magnetic system in Meyers to bias the jaws as desired.

Electromagnets are controlled by current. A lower power setting yields a lower strength magnetic field, and a higher power setting yields a higher strength magnetic field, thus the strength of the electromagnets are controllable. Turning the power source (or controller, magnetic field generator) off deactivates the electromagnets. Also, by reversing the direction of the current applied to the electromagnets reverses the polarity of the magnets which causes a repelling motion as opposed to an attracting motion. Therefore, the combination of Meyers and Hurst suggests a non-mechanically actuated distal portion that is configured to be both attracted and repelled by a magnetic field alone, wherein the strength of electromagnets are variable, the polarity of electromagnets are reversible to attract or repel each other, and the electromagnets are selectively activatable and deactivatable as recited in the claims.

With further respect to claim 7, Hurst suggests the magnetic field of an electromagnet may be changed as desired (for example, see column 6, line 15).

With further respect to claim 33, the magnetizable material is structured as claimed, thus is capable of performing the function recited.

With further respect to claims 34, 36, and 43, the applicant discloses the electromagnets may be used to urge the engaging members open or closed, or a biasing member may be utilized to urge the engaging members open or closed which the electromagnets do the opposing function, thus indicating all three embodiments are merely obvious variations. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device with a biasing member as recited in claims 34 and 36 as a matter of design choice, especially since the embodiment of simply using electromagnets appears to perform equally well.

With further respect to claims 38 and 39, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the magnetizable material from iron since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Claims 17, 19, 35, 54, 58, 60, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. and Hurst as applied to the claims above, and further in view of Fukuda et al. (U.S. Patent No. 5,824,009). Meyers as modified by Hurst discloses the claimed invention except for the apparatus including a needle and suture arrangement, wherein the needle includes a magnetic component. Fukuda also discloses a positioning apparatus comprising engaging members (see entire document). Fukuda teaches providing the apparatus with a needle (3) and suture (3b) arrangement, the needle including a magnetic component (for example, see column 6, lines 10-12), in order to use the apparatus as a suturing device. Meyers discloses the

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apparatus may be utilized as a suture needle holder. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a needle and suture arrangement as taught by Fukuda in Meyers modified device. Doing so would enable the apparatus to effectively suture tissue.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, 58, 60, and 62-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the examined application are anticipated by the patent claims (with the exception of claim 38). Claim 38 would have been obvious over the patent

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claims. Specifically, iron is a well know magnetizable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide iron as the magnetizable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claims 37, 39-43, 46, 49, 50, 56, 57, 59, and 61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2 in view of U.S. Patent No. 3,577,991 (Wilkinson). Here, claims 11-26 of U.S. Patent No. 6,719,765 B2 recites a device for inserting a suture through tissue comprising electromagnets. The device of claims 11-26 differ from claims 37, 39-43, 46, 49, 50, 56, 57, and 59 herein in that it fails to disclose the presence of a pivot connecting the handles and a biasing member for spreading the tissue engaging surfaces. However, Wilkinson discloses an apparatus for moving an implement comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a pivot (12) connecting the handles in order to operate the tissue engaging surfaces and a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Wilkinson to the device of the '765 patent claims would have yielded predicable results and resulted in an improved system, namely, an operable system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging

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surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Conclusion

Applicant's amendment received 24 November 2011 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Primary Examiner, Art Unit 3773
December 14, 2011